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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Complete if Known

Application Number	10/014335
Filing Date	December 11, 2001
First Named Inventor	Fritzberg, Alan
Group Art Unit	1615
Examiner Name	Jones, Dameron

Sheet 1 of 1

Attorney Docket No: 295.044US1

**US PATENT DOCUMENTS**

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T <sup>2</sup>
JP	WO-PCT/AU91/00155	10/31/1991	Turner, Harvey J., et al.	—	—	

**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS**

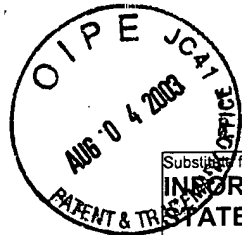
Examiner Initials*	Cite No <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
JP		The Journal of the American Society of Hematology, Vol. 94, No. 10, Suppl 1 (Part 1 of 2), (11-15-1999),	✓
JP		"VII International Multiple Myeloma Workshop", Abstract Book, Stockholm Sweden, (09-1/5-1999), 117	✓
JP		TURNER, J. H., et al., "Samarium - 153 EDTMP therapy of disseminated skeletal metastasis", Eur J. Nucl Med (1989) 15, (1989), 784-795	✓

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Application Number	10/014,335
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Group Art Unit	1616
Examiner Name	Jones, Dameron

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	KABACHNIK et al., "Synthesis and Acid-Base and Complex-Forming Properties of 1,4,7,10 - Tetrakis (dihydroxyphosphorylmethyl) - 1,4,7,10 - tetraazacyclododecane", <u>Bulletin of the Academy of Sciences of the USSR; Division of Chemical Science</u> , <u>33</u> , 777-782 (1984).
	KAPLAN et al., "Therapy of Carcinoma of the Prostate Metastatic to Bone with P32 Labeled Condensed Phosphate", <u>The Journal of Nuclear Medicine</u> , <u>1</u> , 1-13 (1960).
	SCHMIDT et al., "89-Sr for the Treatment of Incurable Pain in Patient with Neoplastic Osseous Infiltrations", <u>Int. J. Clin. Pharmacol</u> , <u>9</u> , 199-205 (1974).

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Group Art Unit	1616
Examiner Name	Jones, Dameron

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## US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
DF	4,897,255	01/30/1990	Fritzberg et al.	424	1.1	06/19/1987
	5,393,512	02/28/1995	Vanderheyden et al.	424	1.53	09/20/1993
	5,679,318	10/21/1997	Vanderheyden et al.	424	1.11	11/21/1994
DF	5,756,685	05/26/1998	Fritzberg et al.	530	391.5	07/12/1996

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## OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

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DF	ANDERSON et al., "High-Dose Samarium-153 Ethylene Diamine Tetramethylene Phosphonate: Low Toxicity of Skeletal Irradiation in Patients with Osteosarcoma and Bone Metastases", <u>Journal of Clinical Oncology</u> , 20, 189-196 (2002).
✓	BENSINGER et al., "166Ho-DOTMP and High-Dose Melphalan before Autologous Peripheral Blood Stem Cell Transplantation in Patients with Multiple Myeloma", Abstract P287; IXth International Workshop on Multiple Myeloma (2003).
✓	BENSINGER et al., "Skeletal Targeted Radiotherapy (STR) with 166Ho-DOTMP plus Melphalan and Autologous Stem Cell Transplant (ASCT) in Multiple Myeloma(MM)", <u>Meeting Proceedings of ASCO</u> , 22, ASCO Annual Meeting, May 2003; Abstract Number 3346, 833 (2003).
✓	BREITZ et al., "Dosimetry of High Dose Skeletal Targeted Radiotherapy (STR) with 166-Ho-DOTMP", <u>Cancer Biotherapy and Radiopharmaceuticals</u> , 18, 225-230 (2003).
✗	DISPENZIERI et al., "A Phase I Study of a Conditioning Regimen for Peripheral Stem Cell Transplantation (PBSCT) for Multiple Myeloma (MM): 153Samarium Ethylenediaminetetramethylenephosphonate (153SM-EDMPT) and Melphalan", <u>Blood</u> , 96, Abstract 2397, 558a (2000).
✗	DISPENZIERI et al., "A Phase I/II Dose Escalation Study of 153-Samarium EDTMP (153-Sm-EDMTP) with Fixed Dose Melphalan Peripheral Stem Cell Transplantation (PBSCT) for Multiple Myeloma (MM)", <u>Blood</u> , 98, Abstract 2855, 682a-683a (2001).
✗	GIRALT et al., "166Ho-DOTMP Plus Melphalan Followed by Peripheral Blood Stem Cell Transplantation in Patients with Multiple Myeloma: Results of Two Phase I/II Trials", <u>Blood</u> , Blood First Edition Paper; DOI 10.1182/2002-10-3250, 1-38 (2003).
✓	GIRALT et al., "Long-Term Follow-Up of 83 Patients with Multiple Myeloma (MM) Treated on a Phase I-II Study of Skeletal Targeted Radiotherapy (STR) Using 166Ho-DOTMP Plus Melphalan with or without Total Body Irradiation (TBI) and Autologous Hematopoietic Stem Cell ...", <u>Blood</u> , 100, 44th Annual Meeting of the American Society of Hematology; Abstract 670, 179a (2002).
DF	HOGAN et al., "Successful Treatment of POEMS Syndrome with Autologous Hematopoietic Progenitor Cell Transplantation", <u>Bone Marrow Transplantation</u> , 28, 305-309 (2001)

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*D Jones*

DATE CONSIDERED

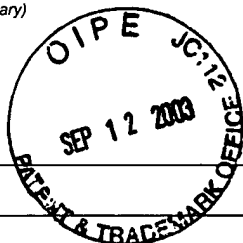
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RA	RAJENDRAN et al., "High-Dose 166Ho-DOTMP in Myeloablative Treatment of Multiple Myeloma: Pharmacokinetics, Biodistribution, and Absorbed Dose Estimation", <u>J Nucl Med</u> , <u>43</u> , 1383-1390 (2002).
WJ	WISEMAN et al., "Bone Targeted Radioisotope Therapy for Treatment of Multiple Myeloma and Bone Tumors", <u>International Journal of Cancer</u> , <u>13</u> , Abstract O 109, 104 (2002).
WJ	WISEMAN et al., "Residual Whole Body 153Samarium Activity Predicts for Successful Autologous Peripheral Blood Progenitor Cell (PBPC) Engraftment Following High Dose 153Samarium Ethylene Diamine Tetramethylene Phosphonate (153Sm-EDTMP) Targeted Radiotherapy", <u>Blood</u> , <u>96</u> , Abstract 1811, 421 (2000). X

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